QUESTIONS CONCERNING CONSENT

(The following is information to help clarify issues of consent. There are also sample consent letters and scripts to help the researcher in the development of his/her own letters and scripts which will meet the IRB requirements. **Please do not attach this section to your application. Attach only the original consent form or script that you have created for your project.**)

Do I need to get consent for archival data? if you are using archived data, consent may not be necessary or even possible. Archival studies still need IRB approval. Some data do not meet the definition of "archived data," but researchers may still seek a waiver of consent requirements. Only studies with a restricted set of conditions may use this option, and each waiver request is separately reviewed and considered by the IRB.

Do I need IRB approval for archival research? Yes. The IRB determines if data were collected in an ethical way.

What is Implied Consent? Implied consent is obtained when subject rights are presented orally, in mail, or by written handout.

What is "participant anonymity" and when should I use it? You should not use a written consent form. Instead you can use a consent script (e.g., phone surveys) or a cover letter (e.g., mail surveys). These documents do the same basic job as a written consent form does informing participants about the study and their rights. The only difference is that participants do not sign their name.

Do I need to get consent if my project is exempt? The requirement for some form of consent applies to ALL research, although most exempt projects (particularly mail or phone surveys) can use a consent script or cover letter (for implied consent).

What if I audio or video tape my participants? You will need to get written consent. The consent procedure needs to specify WHEN the tapes will be destroyed, WHERE they will be stored, and WHO will have access to the tapes.

What are the special consent considerations for children? If a child is between the ages of 7 and 18, then you should seek both written parental and child consent. The consent form language should be at about the same grade level as the child. If the child is between the ages of 3 and 7, then you should use a VERBAL ASSENT, which is a consent script with language appropriate for the child's age. A child younger than age 3 is considered incapable of participating in the consent process. At all age levels, the final power of consent is usually left to the parents or guardians.

What should I do if I suspect a participant or researcher is in trouble? In the course of your research, if you become aware that any specific individual is in imminent danger of harming himself or others (i.e., due to acute depression) or is currently suffering mental or physical abuse, or abusing another you should inform the appropriate authorities. If there is a reasonable chance that you discover such information about your participants, you must tell them of this requirement when you ask for their consent, because the law requires you to break confidentiality in these circumstances. Contact the IRB for more information on this topic, including specific language to be used.

What phone numbers do I have to give participants? You must give participants a number for the IRB as well as for the Faculty Officer responsible for Protection from Research Risks. This should be on all consent forms.

EXAMPLES OF CONSENT FORMS

These hypothetical samples are provided to help you compose your own consent procedure. Decide which form of consent you will need, and then use the appropriate form(s) to make your own. Place the specific information for your project in the appropriate places, as indicated. Once you have written your own version, read it to make sure all the necessary information is there, that there are no mistakes, spelling or grammatical errors, and that it is not ambiguous or otherwise confusing. Below is the Bill of Rights that reflects the philosophy of informed consent and may be included in your consent form.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS

These are the rights of every person who is asked to be in a research study.

The right to be told what the study is trying to find out;
The right to be told what will happen to me and whether any of the procedures, drugs or devices is different from what would be used in standard practice;
The right to be told about the frequent and; or important risks, side effects or discomforts of the things that will happen to me for research purposes;
The right to be told if I can expect any benefit from participating, and, if so, what the benefit might be;
The right to be told of the other choices I have and how they may be better or worse than being in the study;
The right to be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
The right to be told what sort of medical treatment is available if any complications arise;
The right to refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my class grade, university standing, or (if relevant) my right to receive the care I would receive if I were not in the study;
The right to receive a copy of the signed and dated consent form;
The right to be free of pressure when considering whether I wish to agree to be in the study;
The right to receive phone numbers of the IRB as well as the individual responsible for Protection from Research Risks. 3

EXAMPLE COVER LETTER

Dear _____:

The purpose of this study is to survey the types of relaxation activities people often participate in on their own. The results will help therapists determine which relaxation techniques are most appropriate for different individuals. This project has been funded by _____ and is being conducted by _____ in the department of _____ at Roosevelt University. It has been approved by the Roosevelt University Institutional Review Board.

Your name was selected from a list of volunteers who expressed interest in participating in this study. Participation in this study is entirely voluntary and you may choose to discontinue participation at any time without penalty. Your responses to questions will be kept strictly confidential. The identification number at the bottom of the page is only for mailing purposes; no record of these numbers will be retained once the survey is completed and returned. If you would like a copy of the results, please return with the completed survey a note with your address on a separate slip of paper, marked ACOPY OF THE RESULTS REQUESTED." Please do not record this information on the questionnaire itself. Thank you for your time and effort.

If you have any questions, concerns or complaints with this research, feel free to contact us at XXX XXX-XXXX. If you would like to speak with someone other than the researchers, you may contact the Roosevelt University Institutional Review Board at (312) 853-4774. If you have questions about the rights of participants, you may contact the Faculty Research Ethics Officer at (312) 341-2440.

Respectfully, _____

Name, department, address, phone number_____ 4

SAMPLE VERBAL CONSENT SCRIPT

Hello, my name is _____, and I am a student/faculty with the Roosevelt University Department of _____. I am collecting data for my research project on (brief description of subject) under the supervision of (advisor's name). I=d like to ask you for your help by answering a few questions for me regarding (describe subject of questions). Your participation in this survey should take about _____ minutes.

This study involves completing 15 minutes of questionnaires that ask questions about relaxation experiences you may have had. We are interested in exploring the relationship among different types of relaxation experiences.

This research has been reviewed and approved by the Institutional Review Board at RU. If you have any questions, concerns, or complaints about this research project, please contact us at XXX-XXX-XXXX. If you would like to speak with someone other than the researchers, you may contact the Roosevelt University Institutional Review Board at (312) 853-4774. If you have questions about the rights of participants, you may contact the Faculty Research Ethics Officer at (312) 341-2440. The data will be strictly confidential and I will not record your name. Also, your participation is completely voluntary. You are free to not answer any questions you may find objectionable, and may withdraw from my study at any time, just by letting me know you would not like to continue any further.

Are there any questions about my study that I can answer for you at this time? (answer questions). Would you like to participate in my study?

SAMPLE CONSENT FORM

Roosevelt University strongly supports the practice of protection of the rights and safety of research participants. This project is directed by (insert student's name) as a (doctoral/master's/class) project under the supervision of (insert supervisor's name) in the (insert school or college name). It has been reviewed and approved by the Roosevelt University Institutional Review Board. Please read this consent form and decide if you want to participate in our study.

This study compares the effects of two popular professional relaxation techniques on college students. You will be taught one of two widely-used techniques. The technique that you will learn will be chosen randomly, like flipping a coin. You will be asked to attend three weekly training sessions at Roosevelt University. The techniques have few known adverse effects are often used by the public without supervision. However, they require a mild level of exertion (comparable to climbing one flight of stairs) and may temporarily lower metabolic rate. Individuals taking prescription medications affecting metabolic rate should consult their physicians before agreeing to participate.

Each training session lasts 60 minutes. At the beginning and end of each session you will be asked to complete some simple questionnaires that ask you about your thoughts and feelings. The questionnaires will take about 15 minutes to complete. The three sessions will take place:

Monday, September 6, 9 - 10 AM
Monday, September 13, 9-10 AM
Monday, September 20, 9-10 AM
Monday, September 27, 9-10 AM

This experiment poses no known risks to you. Your participation is completely voluntary and your responses will be kept confidential. Your name will not be associated with the data that is collected during the study. You may chose to discontinue at any time without penalty.

The benefit to you is a monetary payment. You will receive $50 at the end of the session for your participation. The benefit to society is that this study will improve our understanding of the effectiveness of relaxation techniques in reducing stress. Upon completion of your participation in this study, you will be provided with a brief explanation of the question this study addresses. If you have any questions not addressed by this consent form, please do not hesitate to ask. You will receive a copy of this form, which you should keep for your records.

CONSENT STATEMENT

The research project and procedures associated with it have been explained to me. I have read and understand the above comments. I am aware that my participation is voluntary and that I may withdraw my consent at any time. I am aware that my condition to participate, or to withdraw from the study, will not affect any other relationship that I may have with Roosevelt University. Confidentiality of records concerning my involvement in this project will be kept in an appropriate manner. When required by law, the records of this research may be reviewed by applicable government agencies.

I have read and understand the above comments and agree to participate in this study. I have received a copy of this consent form for my records. I understand that if I have any questions regarding this project, I can contact Dr. _____ at XXX-XXX-XXXX. If I would rather speak with someone other than the researchers, I may contact the Roosevelt University Institutional Review Board at (312) 853-4774. If I have questions about the rights of participants, I may contact the Faculty Research Ethics Officer at (312) 341-2440.

After reading the entire consent form, if you have no further questions, please sign where indicated.

Participants Signature: _____ Date:
Researcher's Signature: _____Date:

Researcher=s name, office, and phone